Lin v. MetLife

07 civ. 3218

EXHIBIT C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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JEAN LIN,

Plaintiff,

-against- Index No:
07-CV-3218

METROPOLITAN LIFE INSURANCE COMPANY,

Defendant.

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EXAMINATION BEFORE TRIAL of the Defendant, DAVID CLAIN, M.D., taken by the Plaintiff, held at the offices of Trief & Olk, 150 East 58th Street, 34th Floor, New York, New York 10155, on May 28, 2008, at 10:05 a.m., before a Notary Public of the State of New York.

Dr. Kam's office records. The insurance papers that Mr. Lin signed. Hospital records and other doctor's records when he later developed gastric cancer until the time of his death. Dr. Aledort's report, if I didn't mention that again. Those were main documents.

Q. By the way, did the gastric cancer have anything to do with his hepatitis B?

A. No, I don't believe.

Q. So, his death was unrelated to any hepatitis B?

MS. SHERER: Objection to the form.

A. I think his gastric cancer was unrelated. There was an issue which I noted in my report about his development of severe liver changes, you might say liver failure towards the time of his death, as to whether that might have been related to the hepatitis B.

Q. Did he die of gastric cancer?

A. I didn't know the answer to that.

Q. How much time did you spend in preparation of the review of the materials and the writing of the report?

Q. If you have hepatitis B, there are people who clear it themselves, correct?

A. Yes.

Q. There are people who get better through treatment, correct?

A. Yes.

Q. There are people who don't get better, correct?

A. Well, I'm not sure what you mean by that last statement, "don't get better" in which respect?

Q. That the treatment doesn't work, they progress to cirrhosis and they could die.

A. Well, almost always the treatment works, but they could still progress -- who have progressed before they were treated to the point of cirrhosis.

Q. Now, in this particular case, Mr. Lin was successfully treated, correct?

A. Correct.

Q. There was absolutely no evidence of cirrhosis, correct?

A. Correct.

Q. That, if it flared up again in the eyes

I'm not referring to the case of Mr. Lin and how Dr. Kam handled it. I'm just talking in general.

Q. Do you disagree at all with the way Dr. Kam handled Mr. Lin?

A. In terms of reading his record? If there was a fellow of mine, I would heavily critique what he had recorded. But if are asking me, on the ground, do I agree that he didn't need to re-treat Mr. Lin, if that's your question, that is a different question.

Q. Well, let's start with: Did he need to re-treat Mr. Lin?

A. No.

Q. You've got a chance, not only to look at his records, but at his deposition, correct?

A. Yes.

Q. Let me hear your critiques about Dr. Kam's treatment of Mr. Lin.

A. I don't think he recorded on paper what he discussed with Mr. Lin. I don't think he indicated that he ever educated him about hepatitis B. There's nothing in there about his family.

There are a number of issues there, which I record, I teach my training doctors to record. I think it's extremely important that everything you've done with the patient, what I call treatment, is recorded at the time of the visits.

Q. I understand that, but I'm asking you to list all of those. I know you listed some.

Are there any others?

MS. SHERER: Objection to form.

A. Yes. Somewhere along the line, not necessarily every time, that you indicate to the patient what their risks are for the future and what you're doing what you are doing such as sonograms, measurement of tumor markers and so on, the reason why you do those things.

Q. Anything else that you want to list as part of your critique?

A. That would be a short list.

Q. I have plenty of time, so if you want to take a minute to think about it and give me some -- you can list anything else that you might want to critique. I'll wait.

A. No, I think that, essentially, covers

it.

Q. So, it sounds to me that all of the critique was what was recorded, correct? There is no critiquing beyond what was recorded?

A. I'm not critiquing the way in which he prescribed medicines, no.

Q. Well, he only prescribed medicines --

A. Once.

Q. -- for the interferon?

A. Correct.

Q. After that, no medicine was ever prescribed?

A. Correct.

Q. So, do you have any critique at all with anything, other than recording what he said to the patient?

A. No.

Q. There are different things that were being tested during Dr. Kam's treatment of Mr. Lin, correct?

A. Yes.

Q. What were the things that were being tested?

A. So-called liver function tests, E

antigen, E antibody. I think there may have been a re-testing of surface antigens, several tests of hepatitis viral DNA, a viral count, so-called viral count.

I think he did a re-test of sonogram at one point, a couple of times, alpha-fetoprotein -- so-called A-F-P, which is a tumor marker. Those were, essentially, what he was doing.

Q. Now, the longer out you are from successful treatment with interferon, does that in any way indicate a likelihood of reoccurrence or not?

A. I think the longer you're out and have never flared, probably the risk is lower, but that would be just my own gestalt. I'm not sure that I'm quoting any scientific paper on that.

Q. That word, "gestalt," it's not Zimbabwe?

A. It's German.

Q. Do you have any science to support your opinion, or is it just when you're using "gestalt" saying, it's my intuition?

A. No, I don't have a scientific paper.

look for?

A. Yes.

Q. What were the results of the liver function tests that Dr. Kam performed on Mr. Lin?

A. They were normal.

Q. What does that show a doctor who's treating a patient?

A. That the virus continues to replicate at a relatively low level. In other words, the treatment was successful.

Q. Why, if the virus is replicating at a low level, do you still consider the treatment to be successful?

A. We have limited goals in treating hepatitis B, limited because we don't have drugs that can eliminate the virus. So the aim is to reduce viral activity to a level at which there will not be ongoing damage to liver cells, the consequence of which is, firstly, the evolution of cirrhosis and, secondly, because this will increase the risk of liver cell cancer. So we want to keep the liver without inflammation or hepatitis.

Q. It's one of the number of factors, correct?

A. Correct.

Q. What is surface antigen?

A. Surface antigen is really a piece of a virus. So, the presence of surface antigen indicates that there is virus circulating. These are parts of the virus that are being antigenically tested.

Q. What is the purpose of testing viral DNA?

A. Viral DNA is a count of the viruses using a technique called PCR, actual counts of the number of viruses that's evolved. People, back in history, didn't have PCR's, but it since, historically, has changed, but, basically, to answer your question, it's a viral count.

Q. What is the protein alpha-feta that you indicated?

A. Alpha-fetaprotein is a marker that as -- of which -- a whole category of markers that are produced by various tumors.

Alpha-fetaprotein outside pregnancy,

where it is normal, is produced by only one or two tumors, one of which is liver cell cancer. And so, its presence in the serum outside of pregnancy, if it was much elevated, indicate the patient probably has liver cell cancer.

Q. That was negative when tested for Mr. Lin?

A. Yes.

Q. What tests do you, Dr. Clain, rely on in determining whether hepatitis B needs treatment and is active? All of them, some of them, none of them?

A. Let me just get a recap of that. What tests do I do?

Q. I don't care whether you do it or someone else does it, but what tests do you rely on, as a physician, in determining whether hepatitis B needs to be treated and/or in the inactive stage?

A. So, first of all, I'd have to -- you'd have to know they have hepatitis B, surface antigen, you do E antigen and E antibody and liver function profile, mainly for the transaminases. And in cases where there is not

A. An additional zero, a long change.

Q. So, from a hundred to a thousand?

A. Yes.

Q. Or from a thousand to 10,000?

A. Correct. From 120 to 250 is meaningless.

Q. Or from 300 to 500 is meaningless?

A. Yes.

Q. If you go to Page 3 of your report and go to the very first paragraph, do you see the sentence beginning, "He achieved"?

A. Yes.

Q. Could you read that one sentence into the record.

A. "He achieved the primary goals of therapy, which are suppression of hepatitis B viral DNA" -- in quotes -- "viral count, normalization of liver enzymes, AST and ALT and seroconversion to HBeAg-negative."

Q. What do you mean by "suppression of the hep B viral DNA"?

A. That the count came way down from what it was.

Q. What does the word "suppression" mean,

just way down?

A. Yes, because that's all we can achieve as a goal.

Q. So, he achieved the most he could have achieved? Is that what you are saying?

MS. SHERER: Objection to the form.

A. Yes.

Q. The liver enzymes were normal, correct? So, you wouldn't get anything, other than normal; that's the bet you can do, correct?

A. Right.

Q. The seroconversion to HBeAg-negative, that's the best you can do also, correct?

A. Correct.

Q. So, he achieved the best he could do by the treatment he gave?

A. Yes. As I stated there, he achieved the primary goals of therapy.

Q. Do you mean by "primary goals," meaning that he achieved all the goals of therapy or just some of the goals?

A. I guess he achieved all the goals of treatment with interferon, yes.

question I'm asking assumes that everybody has been treated.

A. There's no data. There is no data.

Q. But I'm not talking about --

A. If you're talking about the follow-up of the incidents of cancer in various categories, you know, with and without cirrhosis, you know --

Q. Is there any data comparing the treatment of patients who have been successfully treated with -- for hepatitis B and do not have cirrhosis and never had cirrhosis with the general public's incidents of cancer?

A. Yes, there is data on that.

Q. Where is that data?

A. In what paper?

Q. In what paper.

A. I can't quote you the paper offhand, no.

Q. I've looked at the papers that you've referred to, and all of those papers included in their study people who had cirrhosis, correct?

A. I don't know about that.

treated and so on, all of which are confining factors in the incidents of liver cell cancer.

(Whereupon, the referred to place was read back by the Reporter.)

MR. TRIEF: I move to strike the part that's not responsive.

MS. SHERER: I move to renew.

MR. TRIEF: Off the record.

(Whereupon, an off-the-record discussion was held.)

Q. What is the incidence of liver cancer in the general public?

A. I don't have a number.

Q. Approximately.

A. It's very low.

Q. Tell me.

A. I don't know.

Q. One in a million, one in a thousand, one in a hundred?

A. I don't know. I don't know the number.

Q. What is the incidence rate of liver cancer for those who have been successfully treated for hepatitis B without cirrhosis?

A. It's a few times increased, like three

times increased. It varies in different populations, in different places. It isn't the same here and there. It depends on where the study was done, and there aren't that many studies.

But there is a severalfold increase in liver cancer. I can refer you -- and I refer to that, I think, in one of my comments in the report, is that, if you rook at the AASLD Guidelines on the hepatocellular cancer, they actually quote you papers based on their Asian patients who are not cirrhotic, have no activity, either treated or untreated, are inactive, have an increased instance of hepatocellular carcinoma.

They quote three or four papers. If you look at this AASLD Guidelines, they're quoted here, and they're listed in the paper.

MS. SHERER: Should we mark that as an exhibit?

MR. TRIEF: Sure.

A. If you look in the guidelines -- this is the hepatocellular carcinoma guidelines, not the hepatitis B guidelines. Hepatitis B on

Does it say that anywhere? I mean, is there something that says that?

A. I think there's something that says that. When you get back to Page 1210, "Similarly, the risk of hepatocellular carcinoma" -- "Similarly, the risk of hepatocellular cancer persists in long-term hepatitis B carriers from Asia" -- oh, sorry. I retract. I'm reading the wrong sentence.

Q. The question goes back to the fact that there isn't any comparison in this study of any patients who were successfully treated --

A. No, not successful treatment.

Q. You have to wait for me to finish.

A. Sorry.

Q. You would agree that there isn't anything in this study that refers at all to an analysis of what the incidence is of liver cell cancer for patients who have been successfully treated for hepatitis B, correct?

A. Not in these studies, no.

Q. Liver cancer in the general public, from an instance level, is extraordinarily low, is it not?

A. Very low.

Q. When you are looking at mortality rates, you are looking at other types of cancers and heart disease and things of that nature, correct?

MS. SHERER: Objection to the form.

A. Yes.

Q. The effect of liver cell cancer, because its incidence is so low on mortality rate, is insignificant; wouldn't you agree?

MS. SHERER: Objection to form.

A. No, I wouldn't agree. It's not insignificant for that group of patients. It's very significant.

Q. Obviously, someone who gets liver cell cancer, it is significant for that person. I am talking about, in order to analyze the overall mortality rate of a group of people, liver cell cancer is such a small incidence, that it is insignificant in making that analysis, correct?

MS. SHERER: Objection to form.

A. No, that's not true. Liver cell cancer

A. No, it's not on the bottom of the list, but I can't tell you exactly where it is on the list.

Q. Would you agree that, in looking at the overall mortality rate in the United States, liver cancer is a very low component?

MS. SHERER: Objection.

A. I would prefer to answer that question in a different way.

Q. Could you answer it that way?

A. No, because we're talking here about Asian patients born in Asia, and that's a very different question. The incidents of liver cancer dates in this country from immigrant Asian males is significant.

Q. What is significant --

A. I can't give you a number, but it's a very --

Q. Approximately.

A. I don't have numbers. I don't keep those kind of numbers in my head. I can't give you a number.

Q. In order to say "significant," wouldn't you have to have some approximation?

D. Clain, M.D.

MS. SHERER: Objection to the form.

A. No, I don't need to do that. I can tell you that, just from seeing the patients in my own experience, practice, how often I have seen patients dying of liver cancer.

Q. Isn't that anecdotal?

MS. SHERER: Objection to the form.

A. It may be anecdotal, but it's very significant.

Q. You wouldn't, as a scientist, accept anecdotal information, would you?

MS. SHERER: Objection to the form.

A. I'm simply indicating to you that I know the number is, you know, significant, but I can't quote you the number.

Q. I'm not asking for a quote. I'm asking for any kind of approximation.

MS. SHERER: Objection to the form.

A. I can't give you a number.

Q. Is it fair to say that the basis of your

United States who were immigrants have active disease?

A. Yes, in recent studies in New York City, for example.

Q. What percentage of them have been infected?

A. Higher than that. Probably in the 20 to 30 percent range.

Q. What percentage of Caucasians in the United States have been infected, at one time, with hepatitis B?

A. It varies widely, you know. In other words, it depends on what risk group you fall into.

Q. The overall population.

A. Well, studies don't do overall population because there are great population studies in the United States. It depends on how you selected the people you are testing, you understand.

So, probably you are talking about something like seven or eight -- 7 percent or 6 percent of people -- and I'm hesitating a guess -- have been exposed to hepatitis B.

And a small percent, somewhere under 1 percent -- well under 1 percent -- probably point something percent have active disease.

Q. So something significantly under 1 percent of the Caucasians have what you define as active disease?

A. Yes.

Q. Fifteen to 20 percent of Asians who immigrated here have active disease?

A. Yes.

Q. What is the highest risk group as it relates to hepatitis B in developing liver cancer?

A. Asian men who have active disease who've gone on to develop cirrhosis and have never been treated would be the very highest group.

Q. That was not Mr. Lin?

A. No.

Q. So, if you go to Page 4 of your report and you go down to the last paragraph on Page 4 -- it's an incomplete paragraph, but it's the last paragraph, nonetheless -- do you see what you have in bold print?

A. Right.

maybe 10 percent. I wouldn't consider that a large number.

Q. So, it's how you define the word "large"?

A. Yes.

Q. That was your disagreement with Dr. Aledort?

A. Yes. A large number would have to be a substantial percent, but it isn't.

Q. Then, after that reference, you indicate that, children become chronic carriers with all the long-term risks of liver damage and liver cell cancer and that's because they're not treated in Asia, correct?

That's the point you're making?

A. I'm not making a point that they're not treated, but anyone who's chronically infected has those risks.

Q. It's because they've developed cirrhosis, correct?

A. In terms of evolving to liver damage, if they're treated before that, yes, you can prevent that. But we don't know what the effect is of treatment in preventing liver

cancer.

Q. The sentence there is assuming, though, that these children in Asia are not being treated; am I correct?

Is that your assumption on Page 5?

A. All I'm saying is, if you become a chronic carrier, these are your risks. I am not implying treatment or no treatment. Once you get into a chronic situation, these are the risks. Now, obviously, any competent physician would intervene, but that's not my point. Once you develop hepatitis B, these are the risks in front of you.

Q. Why would you intervene if the intervention doesn't do anything for the patient?

A. How do you mean? I don't understand the question.

Q. My apologies.

Doesn't the intervention help the patient, and isn't its purpose to help the patient?

A. I think we're talking at cross purposes here. That statement was made simply to

approximate number?

MS. SHERER: Objection to form.

A. Yes, there are studies, but I can't quote you the numbers.

Q. Do you know the name of any study that would give me approximate risk of death from liver cell cancer for successfully treated --

A. Not for successfully. I don't think there is any data on successfully treated patients. That group we talked about previously, I don't believe that there are any long-term studies on that.

Q. So, with respect to Mr. Lin, are there any studies which would indicate what his risk of death from liver cell cancer would be?

A. Precisely, no.

Q. Approximately.

A. No. I don't think anyone can give you a number.

Q. Is the use of the word "significant" that you're using here strictly anecdotal?

MS. SHERER: Objection to form.

A. No, because there are many, many studies reported of people in his situation who have

ethnicity. I believe there are legal issues about this.

So, would we test everybody for hepatitis B who's going for insurance? That is an insurance company question for the insurance company. If you ask me, what would I do in my medical office, the answer is different.

Q. What would you do in your medical office?

A. In my medical office, if someone was an Asian immigrant, if I was a primary care doctor, I would test them for hepatitis B.

Q. When would you begin to treat a patient for hepatitis B when using the various test results we have for Mr. Lin?

At what numbers? And we could refer to the viral DNA and the E antigen and liver function tests. When would you begin to retreat him?

A. First, we'd need to have an elevated DNA level, significantly elevated, which at least in excess of a hundred thousand.

Q. Did he have --

A. Yes, he had millions.

Q. At any point from looking at the data that you saw, should he have been retreated?

A. No.

Q. So, from looking at the data that you saw, would you agree that the treatment for the entire time that you had data was successful?

A. Medical drug treatment, yes.

MR. TRIEF: Let's take a few minutes.

(Whereupon, a recess was taken.)

Q. You indicated earlier that you don't have any idea whether successfully treated hepatitis B patients in the United States have a lower mortality rate --

MS. SHERER: Objection to the form.

Q. -- or you do, than people who are not infected?

Do you have any idea?

A. Sorry. Can you just restate that.

Q. I'm sorry. It was my fault. It wasn't your fault.

I am talking significantly now. Is there any significant difference in mortality

between a successfully treated hepatitis B patient than the general public?

A. Yes, there is a difference between the two.

Q. Do you know what it is?

A. I don't know.

You asked me that before.

Q. Would you be able to tell if it was significant or insignificant?

A. Yes. I believe the numbers for both treated patients and those who never been treated are inactive, but I think they're whatever -- are several times those who are not infected. I can't give you have a number.

Q. But "several times" doesn't measure the mortality.

A. I can't give you the mortality.

Q. It's the mortality part I'm talking about.

Let's say the average American lived to 72. The person who is infected, but treated successfully, would that person live to 65 or 71.3? Would you be able to give me any range?

A. Yes. Let me just explain some of the